

PHARMACY POLICY STATEMENT

Ohio Medicaid

DRUG NAME	Probuphine (buprenorphine subdermal implant)
BILLING CODE	J0570
BENEFIT TYPE	Medical
SITE OF SERVICE ALLOWED	Office
COVERAGE REQUIREMENTS	Prior Authorization Required (Non-Preferred Product) QUANTITY LIMIT— 1 implant in each arm for 6 months each
LIST OF DIAGNOSES CONSIDERED NOT MEDICALLY NECESSARY	Click Here

Probuphine (buprenorphine subdermal implant) is a **non-preferred** product and will only be considered for coverage under the **medical** benefit when the following criteria are met:

Members must be clinically diagnosed with one of the following disease states and meet their individual criteria as stated.

OPIOID DEPENDENCE

For **initial** authorization:

1. Member is 18 to 65 years of age; AND
2. Member has a documented diagnosis of opioid use disorder and/or other dependency in char notes; AND
3. Medication must be prescribed by a DATA 2000 waived physician with an appropriate DEA number associated with an "X" prefix or SAMHSA certified; AND
4. Member must participate in a comprehensive rehabilitation program that includes psychosocial treatment (Documentation of treatment plan and taper strategy not required, but verification upon request must be provided); AND
5. Member must have achieved and sustained prolonged clinical stability on 8 mg/day or less of transmucosal buprenorphine equivalent for at least 3 months without any need for supplemental doses or adjustments. The dose should not have been tapered down to a lower dose for the sole purpose of transitioning to the subdermal implant; AND
6. A documented reason as to why oral therapy should not be continued; AND
7. All REMS Program criteria must be met (see www.probuphinerems.com).
8. **Dosage allowed:** 1 implant in one arm for 6 months, 1 implant in the opposite arm for a total of 12 months of therapy. Implants should not be used for additional treatment cycles after one insertion in each upper arm.

Note: Use of buprenorphine subdermal implant (Probuphine) is limited to a total duration of 12 months (1 implant in each arm for 6 months each).

If member meets all the requirements listed above, the medication will be approved for 12 months.

For **reauthorization**:

1. Probuphine will not be reauthorized.



CareSource considers Probuphine (buprenorphine subdermal implant) not medically necessary for the treatment of the diseases that are not listed in this document.

DATE	ACTION/DESCRIPTION
06/21/2018	Policy for Probuphine modified into a new format.

References:

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2. Probuphine [package insert]. Princeton, NJ: Braeburn Pharmaceuticals, Inc.; May 2016.
3. Substance Abuse and Mental Health Services Administration, Office of Applied Studies (2008). US Dept of Health and Human Services. Results from the 2007 National Survey on Drug Use and Health: National Findings. (NSDUH Series H-34, DHHS Publication No. SMA 08-4343). Rockville, MD.
4. Kakko J, Heilig M, Sarman I. Buprenorphine and methadone treatment of opiate dependence during pregnancy: Comparison of fetal growth and neonatal outcomes in two consecutive case series. *Drug Alcohol Depend.* 2008 Jul 1; 96(1-2):69-78.
5. Maremmani I and Gerra G. Buprenorphine-based regimens and methadone for the medical management of opioid dependence: selecting the appropriate drug for treatment. *Am J Addict* 2010;19: 668-568.
6. Nicholls L, Bragaw L, and Ruetsch C. Opioid dependence treatment and guidelines. *J Manag Care Pharm.* 2010 Feb;16(1 Suppl B):S14-21.
7. Jones HE, Martin PR, Heil SM, et al. Treatment of opioid dependent pregnant women: clinical and research issues. *J Subst Abuse Treat* 2008; 35(3): 245-259.
8. Orman JS, Keating GM. Buprenorphine/naloxone: a review of its use in the treatment of opioid dependence. *Drugs.* 2009; 69(5):577-607.
9. Drug Enforcement Administration Office of Diversion Control. DEA requirements for DATA waived physicians (DWP). http://www.deadiversion.usdoj.gov/pubs/docs/dwp_buprenorphine.htm.
10. Substance Abuse and Mental Health Services Administration. Buprenorphine Waiver Management. Updated 8/17/16. <http://www.samhsa.gov/medication-assistedtreatment/buprenorphine-waiver-management>.
11. Ohio. 5122-29-35. Licensure to conduct an opioid agonist program.
12. Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-5)
13. Ohio Administrative Code 4731-11.
14. Kampman K, Jarvis M. American Society of Addiction Medicine (ASAM) National Practice Guideline for the Use of Medications in the Treatment of Addiction Involving Opioid Use. *J Addict Med.* 2015; 9: 1-10.

Effective date: 08/31/2018

Revised date: 06/21/2018